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**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**21 CFR Part 1308**

**[Docket No. DEA-581]**

**Schedules of Controlled Substances: Placement of Cenobamate in Schedule V**

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Final rule.

**SUMMARY:** This final rule adopts, without change, an interim final rule with request for comments published in the *Federal Register* on March 10, 2020, placing cenobamate [(1R)-1-(2-chlorophenyl)-2-(tetrazol-2-yl)ethyl] carbamate, including its salts, in schedule V of the Controlled Substances Act (CSA). With the issuance of this final rule, the Drug Enforcement Administration maintains cenobamate, including its salts, in schedule V of the CSA.

**DATES:** The effective date of this rulemaking is [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**FOR FURTHER INFORMATION CONTACT:** Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (571) 362-3261.

## **SUPPLEMENTARY INFORMATION:**

### **Background and Legal Authority**

Under the Controlled Substances Act (CSA), as amended in 2015 by the Improving Regulatory Transparency for New Medical Therapies Act (Pub. L. 114-89), when the Drug Enforcement Administration (DEA) receives notification from the Department of Health and Human Services (HHS) that the Secretary has approved a certain new drug and HHS recommends control in the CSA schedule II-V, DEA is required to issue an interim final rule, with opportunity for public comment and to request a hearing, controlling the drug within a specified 90-day timeframe and subsequently to issue a final rule. 21 U.S.C. 811(j). When controlling a drug pursuant to subsection (j), DEA must apply the scheduling criteria of 21 U.S.C. 811 (b) through (d) and 812(b). 21 U.S.C. 811(j)(3).

On March 10, 2020, DEA published an interim final rule in the *Federal Register* to make cenobamate (including its salts) a schedule V controlled substance. 85 FR 13741. The interim final rule provided an opportunity for interested persons to submit comments, as well as file a request for hearing or waiver of hearing, on or before April 9, 2020. DEA received two comments and did not receive any requests for hearing or waiver of hearing.

### **Comments Received**

In response to the interim final rule, DEA received two comments. One comment was blank and the second comment was not related to the scheduling of cenobamate. Therefore, DEA has no responses to those comments.

Based on the rationale set forth in the interim final rule, DEA adopts the interim final rule, without change.

**Requirements for Handling Cenobamate.**

As indicated above, cenobamate has been a schedule V controlled substance by virtue of an interim final rule issued by DEA in March 2020. Thus, this final rule does not alter the regulatory requirements applicable to handlers of cenobamate that have been in place since that time. Nonetheless, for informational purposes, we restate here those requirements. Cenobamate is subject to the CSA's schedule V regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, dispensing, importing, exporting, research, and conduct of instructional activities and chemical analysis with, and possession involving schedule V substances, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) cenobamate, or who desires to handle cenobamate, must be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312. Any person who intends to handle cenobamate, and is not registered with DEA, must submit an application for registration and may not continue to handle cenobamate, unless DEA has approved that application for registration, pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312.

2. *Disposal of stocks.* Any person who obtains a schedule V registration to handle cenobamate and subsequently determines they are no longer willing or able to

maintain such registration must surrender all quantities of currently held cenobamate, or may transfer all quantities of cenobamate to a person registered with DEA in accordance with 21 CFR part 1317, in addition to all other applicable Federal, State, local, and tribal laws.

3. *Security.* Cenobamate is subject to schedule III-V security requirements and must be handled and stored in accordance with 21 CFR 1301.71–1301.93. Non-practitioners handling cenobamate must also comply with the employee screening requirements of 21 CFR 1301.90–1301.93.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of cenobamate must comply with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302.

5. *Inventory.* Since March 10, 2020, every DEA registrant who possesses any quantity of cenobamate was required to keep an inventory of cenobamate on hand, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records and Reports.* DEA registrants must maintain records and submit reports for cenobamate, or products containing cenobamate, pursuant to 21 U.S.C. 827, and 958(e), and in accordance with 21 CFR parts 1304, 1312, and 1317.

7. *Prescriptions.* All prescriptions for cenobamate, or products containing cenobamate, must comply with 21 U.S.C. 829, and be issued in accordance with 21 CFR parts 1306 and 1311, subpart C.

8. *Manufacturing and Distributing.* In addition to the general requirements of the CSA and DEA regulations that are applicable to manufacturers and distributors of

schedule V controlled substances, such registrants should be advised that (consistent with the foregoing considerations) any manufacturing or distribution of cenobamate may only be for the legitimate purposes consistent with the drug's labeling, or for research activities authorized by the Federal Food, Drug, and Cosmetic Act and the CSA.

9. *Importation and Exportation.* All importation and exportation of cenobamate must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

10. *Liability.* Any activity involving cenobamate not authorized by, or in violation of, the CSA or its implementing regulations, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

## **Regulatory Analyses**

### *Administrative Procedure Act*

This final rule, without change, affirms the amendment made by the interim final rule that is already in effect. Section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553) generally requires notice and comment for rulemaking. However, 21 U.S.C. 811(j) provides that in cases where a certain new drug is: (1) Approved by HHS and (2) HHS recommends control in CSA schedule II–V, DEA shall issue an interim final rule scheduling the drug within 90 days. Additionally, subsection (j) specifies that the rulemaking shall become immediately effective as an interim final rule without requiring DEA to demonstrate good cause. DEA issued an interim final rule on March 10, 2020, and solicited public comments on that rule. Subsection (j) further provides that after giving interested persons the opportunity to comment and to request a hearing, the Attorney General, as delegated to the Administrator of DEA, shall issue a final rule in

accordance with the scheduling criteria of 21 U.S.C. 811(b) through (d) and 812(b). As stated above, the two public comments DEA received to the interim final rule did not necessitate any response. DEA is now issuing the final rule in accordance with subsection (j).

*Executive Orders (E.O.) 12866, 13563, and 13771, Regulatory Planning and Review, Improving Regulation and Regulatory Review, and Reducing Regulation and Controlling Regulatory Costs*

In accordance with 21 U.S.C. 811(a) and (j), this scheduling action is subject to formal rulemaking procedures performed “on the record after opportunity for a hearing,” which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the procedures and criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of E.O. 12866 and the principles reaffirmed in E.O.13563.

This final rule is not an E.O. 13771 regulatory action pursuant to E.O. 12866 and OMB guidance.<sup>1</sup>

*E.O. 12988, Civil Justice Reform*

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

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<sup>1</sup> Office of Mgmt. & Budget, Exec. Office of The President, Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017 Titled “Reducing Regulating and Controlling Regulatory Costs” (Feb. 2, 2017).

*E.O. 13132, Federalism*

This rulemaking does not have federalism implications warranting the application of E.O. 13132. The rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

*E.O. 13175, Consultation and Coordination with Indian Tribal Governments*

This rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

*Regulatory Flexibility Act*

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601-612) applies to rules that are subject to notice and comment under section 553(b) of the APA. As noted in the above discussion regarding the applicability of the APA, DEA was not required to publish a general notice of proposed rulemaking. Consequently, the RFA does not apply.

*Unfunded Mandates Reform Act of 1995*

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.*, DEA has determined that this action would not result in any Federal mandate that may result “in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any 1 year.” Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

*Paperwork Reduction Act of 1995*

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action does not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

*Congressional Review Act*

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. This rule will not result in: An annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based companies to compete with foreign-based companies in domestic and export markets. However, pursuant to the CRA, DEA has submitted a copy of this final rule to both Houses of Congress and to the Comptroller General.

**List of Subjects in 21 CFR Part 1308**

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

Accordingly, the interim final rule amending 21 CFR part 1308, which published on March 10, 2020 (85 FR 13741), is adopted as final without change.

**Timothy J. Shea,**  
*Acting Administrator.*



